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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,022	05/04/2001	Joseph D. Gold	091/005P	7806

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EXAMINER

TON, THAIAN N

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 10/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/849,022

Applicant(s)

GOLD ET AL.

Examiner

Thaia N. Ton

Art Unit

1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10 September 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: 1-3, 6, 8, 9, 13, 15-36

Claim(s) withdrawn from consideration: _____

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____

Joe Winters
AU 1632

Continuation of 5. does NOT place the application in condition for allowance because: The amendments to the claims fail to overcome the prior rejections set forth in the prior Office action, mailed 6/10/04. The double patenting rejection of claims 1-3, 8 and 9, over Application No. 09/530,346, is maintained as no terminal disclaimer or cancellation of the copending claims has been made of record. The prior rejection of claims 1-3, 8, 9, 13, 15-36 is maintained for reasons of record advanced in the prior Office action. Applicants argue that the amendment overcomes these rejections because 1) it is important to separate the product claims from claims covering a process for obtaining the product and 2) the methods for making genetically altered cells indicates that the cells are "maintained" during genetic alteration and thus, the claims do not require that the cells be maintained in an undifferentiated state. First, Applicants argue that because it is well-established in law that the specification need not teach all possible ways of making a claimed product, as long as one method of making the product is provided. Thus, the cell populations as claimed (claims 8, 9, 13, 15-36) are enabled by the population because one method of producing them is provided by the specification. See p. 7 of the Response. This is not persuasive. Although it is acknowledged that Applicants need not provide all possible ways of making a claimed product, the method in which the claimed product is made must be enabling. This is not the instant case. The specification does not provide any teachings or guidance for culturing hES cell in a culture environment without fibroblast conditioned medium in the presence of an extracellular matrix. Furthermore, it is noted that, for example, claim 1 recites that the hES cells express the protein while undifferentiated (see last sentence). Thus, the claims require that the hES cells, after transfection, be cultured such that they are undifferentiated. The instant specification provides no teachings or guidance with regard to specific conditions such that the hES cells would be undifferentiated when only cultured on an extracellular matrix absent fibroblast-conditioned media. See prior Office action, pp. 4-5. Thus, the prior rejection is maintained. It is noted that Applicants state that the claims do not require the cells to be maintained in an undifferentiated state, and point to step c) of the independent claims 1 and 17 which explicitly require the cells to become differentiated. It is noted that there does not appear to be a step c in claim 1. Further, in order to enable claim 17, the hES cells which are maintained on the extracellular matrix would require fibroblast-conditioned medium to maintain their undifferentiated state (and thus be called hES cells), therefore, as stated previously, the claims require the recitation of fibroblast-conditioned medium to enable them.